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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,596	08/31/2001	Nobuko Yamamoto	35.C15718	7458
5514	7590	08/01/2006	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			FREDMAN, JEFFREY NORMAN	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 08/01/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/942,596

Applicant(s)

YAMAMOTO ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 9-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-6 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Gingeras et al (U.S. Patent 6,228,575).

Gingeras teaches a method of claims 1, 2, 9 and 10 for identifying an unknown base sequence present in a target single stranded nucleic acid (see abstract) comprising the steps:

(a) preparing a probe array in which single stranded nucleic acid probes are arranged as isolated spots on a substrate, the probes each having a base sequence complementary to one of plural base sequences expected to be the unknown base

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sequence (see figures 6 and 7, column 33, lines 55-60 and columns 17 and 18, for example),

(b) reacting a single stranded nucleic acid, which has a base sequence fully complementary to a base sequence of one of the single stranded nucleic acid probes and is fluorescence labeled with the probe array under conditions that single stranded nucleic acids complementary to each other form a double stranded nucleic acid (see figure 26, column 33, lines 15-40 and column 10, for example)

removing the unreacted labeled single stranded nucleic acid (see column 33, lines 33-35),

measuring fluorescence intensity of each spot of the probe array to obtain a first template pattern showing a relationship between location of the probes and fluorescence characteristics (see figures 21-23, column 33, lines 39-41 and table 2)

(c) performing the same operation as the step (b) for each of the remaining single stranded nucleic acid probes and obtaining template patterns of each probe showing a relationship between location and fluorescent characteristics of the probes (see figures 21-22, column 10, lines 40-67 and column 33, line 54 to column 34, line 15 "A total of 25 M. tuberculosis isolates were analyzed"),

(d) performing the same operation as step (b) using a sample containing the target single-stranded nucleic acid of unknown base sequence to obtain a sample pattern showing relationship between a position and fluorescent characteristic (see figures 21-22, column 10, lines 40-67 and column 32, lines 55-67)

(e) comparing the sample pattern obtained in step (d) with a plurality of image template patterns, the plurality of image template patterns comprising the first image template pattern and the image template patterns from No.2 to No. n to find an image template pattern substantially identical to the sample pattern (see column 10, lines 40-45 "This chip based screening method allows one to build up a database of hybridization patterns corresponding to different species. Some regions of the hybridization pattern will be shared among subsets of the species because their sequences in regions corresponding to those hybridizations are identical. Other regions of the hybridization pattern will differ between two species because the sequence corresponding to those hybridizations are different. In all cases, the sequences of the rpoB gene of the unknown species are being compared to the corresponding sequence of Mt. Differences in the hybridization pattern of a particular species to the pattern observed with Mt as sample, can be correlated to the presence of a polymorphism at a particular point in the sequence of that species.") (Also see column 34, table 2 and lines 45-67 and figure 15 and figures 22-23 where patterns were compared, for additional exemplary discussions of the pattern comparison),

(f) identifying the base sequence of the single stranded nucleic acid used for the preparation of the identified image template pattern as the base sequence of the target (see column 10, lines 40-67, column 33, line 54 to column 45, line 6 and column 34 lines 34-67, for example).

Gingeras further analyzed the probe arrays to calculate a mean value of fluorescent intensities and then a difference was calculated between the fluorescence intensity of a reference array without a mismatch and the mean value of fluorescent intensities of the double stranded nucleic acids having a one or greater base mismatch (see column 38, lines 33-67) and

(g) Gingeras analyzes each of the positions to show a relationship between location and the fluorescent characteristics of the probes (see column 10, lines 40-67 and column 38, line 45 to column 40, line 25, for example).

(h) Gingeras compares the sample pattern obtained from the unknown with the known sample pattern to identify the base sequence (see column 10, lines 40-67 and columns 34-46, inclusive).

With regard to claim 3, Gingeras determines a two valued pattern with a threshold intensity value where a mean value was used (see column 26, lines 5-25, where values were normalized to a histogram and in which 50 counts over background and where Gingeras states "The histogram has a mesh size of 0.01, and was smoothed by replacing the value at each point with the average number of counts over a five-point window centered at that point (see column 26, lines 13-15)" where the word "average" is the "mean".).

With regard to claims, 4 and 5, Gingeras teaches probes in the range from 15 nucleotide oligomers (see SEQ ID NO:3, for example and column 41, line 67 and column 4, lines 63-65).

With regard to claim 6, Gingeras teaches single base pair mismatch detection (see column 29, line 54 to column 30, line 48, for example).

With regard to claim 11, the claim requires comparison of a single mismatch as a threshold as compared with two mismatches. Gingeras teaches single mismatch analysis (see column 26, line 2, for example).

Response to Arguments

3. Applicant's arguments filed June 26, 2006 have been fully considered but they are not persuasive.

Applicant argues that Gingeras does not teach the features of the claims, but does not point to a specific feature that is not taught by Gingeras. The rejection specifically identifies teachings of Gingeras. A similar fact pattern exists for the dependent claims. Therefore, the rejection is maintained.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey Fredman
Primary Examiner
Art Unit 1637

7/28/06